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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,367	12/28/2001	Larry R. Green	005593.P004	2085

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EXAMINER

WALSH, DANIEL I

ART UNIT	PAPER NUMBER
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2876

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/035,367

Applicant(s)

GREEN, LARRY R.

Examiner

Daniel I Walsh

Art Unit

2876

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,7-9,12,14,15 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 8, 9, 12, 14, 15, and 17-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 5-03.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of the Amendment received on 11 July 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling for placing substrates on a platen by a computer before transfer to the item. The specification is not enabling for substrates for labels and spots, and why, how and for what purpose substrates are placed on platen, which typically holds glass slides, before transfer to an item.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 18 recites the limitation "the substrates" in line 1. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The use of the term substrates renders the claim vague/indefinite. It is unclear to the examiner how labels and spots include substrates, and why the substrates are placed on platen before transfer to an item. Typically in the art, platens are used to hold slides, and the examiner is unclear why one would transfer substrates by a computer, to a platen before transferring to an item.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 17, 20-22, 7-9, 12, 14, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles (US 2002/0028457).

Re claim 17, microarray and assaying technology is well known and conventional in the art for genetic research. Empedocles teaches assays that allow for the detection of a single copy of a target of interest, where the species is either directly or indirectly labeled with a semiconductor nanocrystals (abstract). Empedocles et al. teaches the use of a calibration spot,

and array spots (interpreted to include sample spots including detector molecules, as is well known and conventional in the art), (paragraph [0110]). The Examiner has interpreted the fluorescent nanocrystals as luminescent labels, since they are luminescent and used to label/identify compounds. Though Empedocles is silent to the label, calibration spots, and sample spots being attached using an aldehyde cross linking group, the examiner notes that aldehyde cross linking group/covalent attachment means, are well known and conventional in the art as a way of immobilizing a protein, genetic fragment, etc. (detector molecule) to a solid phase, as long as the necessary available functional groups are available, and by using the appropriate cross-linking reagent (see 2004/0063,174 and EP000140489A1). Accordingly, it is well known and conventional to use an aldehyde cross linking group for such attachment means, and therefore obvious to one of ordinary skill in the art to provide predictable results.

Re claims 20-21, it is well known and conventional to prepare glass slides (US 2002/0028457 and US 2001/0044132), as is well known and conventional in the art to spot (see below as well).

Re claim 22, it is well known and conventional that glass slides can include waveguides. Further, it is well known to use waveguides for use in biosensor arrays, for example.

Re claim 7, it is well known and conventional that different sample spots contain different detector molecules, such as in the case of microarrays (paragraph [0002]+ and US 2001/0044132), as is well known and conventional in the art.

Re claim 8, it is well known and conventional in the art that the detector molecules can be antibodies, proteins, gene fragments, etc., depending on what is being tested for.

Re claim 9, as discussed above, detector molecules are exposed to target compounds for detection, as is well known and conventional in the art for microarrays, for example, where detector and targets are combined in order to determine compounds.

Re claim 12, as discussed above, detector molecule:target compound complexes are created when a target is combined with a detector molecule, and the complex can be determined electronically. One means of determination includes fluorescent labels, and imaging using detectors to detect the presence of such labels, and hence detect compounds through the analysis of the signal, as is well known and conventional in the art.

Re claims 14-16, as discussed above, sensors are used to determine the concentration of compounds by comparing the sample spot luminescence to calibration spot luminescence, and that the sensor effectively reads the label by imaging its spectral emission to identify the item.

Re claims 20-21, it is well known and conventional to prepare glass slides (US 2002/0028457 and US 2001/0044132).

Re claim 22, it is well known and conventional that glass slides can include waveguides. Further, it is well known to use waveguides for use in biosensor arrays, for example.

7. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles, as discussed above, further in view of Richards (US 2003/0108868).

The teachings of Empedocles have been discussed above.

Empedocles is silent to how to spot.

Re claims 18-19, it is well known and conventional in the art to control spotting using a robot/computer means. Specifically, Richards teaches the use of computer means to control placement of compounds on a slide (FIG. 2 and paragraph [0031] +). Though Richards is silent

to the placement of calibration spots, it is well known and conventional in the art to place calibration spots, target, samples, etc. on a slide/medium as discussed above. Therefore, it is well known in light of sample/reagent application by computer to apply calibration spots by computer, in order to comply with spotting means that are well known and conventional in the art (walk away/automated/robotic/computerized, etc.) that produce predictable results, and therefore one would be motivated to combine the teachings of Empedocles with those of Richards in order to have an automated and reliable means of combining. Re claim 19, the examiner notes that it is well known and conventional in the art to use a computer/robot to control reagent or sample application.

The Examiner notes that he interpreted "substrates for the label, calibration spots, and sample spots" (re claim 18), as the compounds used for the label/spots. Further, the Examiner has interpreted platen as a through holes/well, which is used in an array to hold samples.

8. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Empedocles in view of Crosby (US 2002/0124738).

The teachings of Empedocles have been discussed above.

Re claim 5, Empedocles et al. is silent to the label being a barcode.

Crosby (US 2003/0124,738) teaches the use of a diagnostic test strip that provides machine-readable results in the form of a barcode.

At the time the invention was made, it would have been obvious to an artisan of ordinary skill in the art to combine the teachings of Empedocles et al. with those of Crosby.

One would have been motivated to do this in order to have test results that can be read by machine (not manually) and therefore is more efficient.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Houts (US 2001/0044132), Zhu (US 2004/0063174), and Sakata et al. (EP000140489A1).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel Walsh whose telephone number is (571) 272-2409 (as of January 15, 2004). The examiner can normally be reached between the hours of 7:30am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Lee can be reached on (571) 272-2398. The fax phone numbers for this Group is (703) 872-9306, (703) 308-7724, or (703) 308-7382.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [daniel.walsh@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

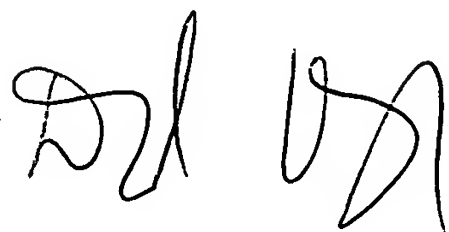
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0956.

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D. Walsh

Handwritten signature of D. Walsh, consisting of stylized initials.

DW
4-1-04

Handwritten signature of Karl D. Frech, featuring a large, stylized 'K' and 'F'.

KARL D. FRECH
PRIMARY EXAMINER